



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,517	10/16/2003	Edgar Hommann	33628/US	5234

7590 03/30/2007
David E. Bruhn
DORSEY & WHITNEY LLP
Intellectual Property Department
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498

EXAMINER

MEHTA, BHISMA

ART UNIT	PAPER NUMBER
----------	--------------

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/687,517

Applicant(s)

HOMMANN ET AL.

Examiner

Bhisma Mehta

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-14, 16, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-14, 16, 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2007 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on January 16 2007. These drawings are not all acceptable. The replacement drawing for Figure 2d is not acceptable because one of the reference characters (17 or 17') is still unclear as to whether this reference character is 17 or 17'. It should be noted that reference character 17' is not described in the specification. The replacement drawings for the other figures are acceptable. However, it appears that reference character 17 in Figures 4a and 4b should be changed to 317 to reflect the scale drum 317 as shown in amended Figure 3 and in the amended specification. Appropriate corrections to the figures should be made.

Specification

2. The disclosure is objected to because of the following informalities: The sentence beginning "In some embodiments..." in line 28 of page 14 appears to have a grammatical error. Appropriate correction is required.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to mention the operating means having a lever portion and a lever arm portion provided at a fixed angle with respect to the lever arm portion and the lever arm portion extending from the lever portion along the casing to a casing attachment point (or attachment point) where the lever arm portion is attached to the casing. The specification also fails to mention the needle

Art Unit: 3767

protector comprising a sleeve that slides axially with respect to the holder or product container and where the sleeve guides positioning of a needle cap used to attach or detach the injection needle. The specification fails to mention the injection device as having an operating assembly, a dispensing assembly, or a releasing means. It is suggested that the claims be amended to use language, which is already established in the specification. For example, the specification does not mention a releasing means but does disclose a dosage means and a release element.

Claim Objections

4. Claims 1-9, 12, and 13 are objected to because of the following informalities: Claim 1 recites the limitation "the dispensing mean" in line 12. Claims 6 and 13 recite the limitation "said fluid product" in line 2. There is insufficient antecedent basis for these limitations in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 9, it is unclear if another indicator for indicating a product amount is being claimed in addition to the indicator for indicating a

Art Unit: 3767

product amount already established in claim 6 or if the indicator in claim 9 is the same as the indicator in claim 6.

7.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-5, 14, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Stradella (U.S. Patent No. 7,011,234). Stradella discloses a device for administering a fluid product having a casing (1), dispensing means (20), and operating means or an operating assembly. The operating means or operating assembly has a lever portion which comprises a protrusion co-operable with the dispensing means via a surface (16, 51) oblique relative to a longitudinal axis of the casing and a lever arm portion (50)

Art Unit: 3767

provided at a fixed angle with respect to the lever portion. The lever arm portion extends from the lever port along the casing to a casing attachment point. The operating means is pivotable in a radial direction relative to the casing and movement of the protrusion along the oblique surface displaces the dispensing means as disclosed in lines 26-44 of column 3. The connection of the protrusion to the dispensing means is considered to be a T-connection where the axis of the protrusion and the dispensing means are considered to form a T-connection. The device also has an indicator (30 or 80) for indicating a product amount.

10. Claims 6, 7, 9, 12, 17, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Cosmai (U.S. Patent No. 4,850,967). Cosmai discloses an injection device having a casing (24), dispensing means (29), and operating means (13). The operating means are provided laterally on a circumferential surface of the casing and are pivotable in a radial direction about a fulcrum (45) which is arranged laterally on the injection device. The operating mean also comprises a protrusion which is co-operable with the dispensing means via a surface oblique relative to a longitudinal axis of the casing. The protrusion of the operating means can be considered to be any portion of the operating means which has a surface which is oblique relative to the longitudinal axis of the casing. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. The fulcrum is provided on the circumferential surface in a generally central area of the injection device. In lines 17-43 of column 7, Cosmai discloses an indicator (47, 50) in the form of a slider and graduation markings indicating a product amount in the product container. Pivoting the operating means which causes

Art Unit: 3767

the dispensing means to be advanced, thus moving the slider, operates the indicator.

The injection device also includes a dosing means with a releasing element (56) which projects through an opening in the casing. The releasing element is moved from a first stopper on the opening which is where the element contacts a portion of the opening to a second stopper on the opening which is where the element contacts another portion of the opening when the element is in its moved position. The dimensions of the opening limit the movement of the releasing element in accordance with a dose amount. The indicator comprises a scale (i.e. the markings) and count down by a dosage unit when the dispensing means are operated. As to claim 12, a guiding means is provided which is capable of guiding the positioning of a cap. As to claim 19, the sleeve (16) is considered to be capable of surrounding an injection needle and being shiftable.

11. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Shaw et al (U.S. Patent No. 7,118,552). Shaw et al disclose an injection device for administering a fluid product having a casing (50), a holder (20), an injection needle (430), and a needle protector (30) where the needle protector comprises a sleeve to generally surround the injection needle in an advanced position. The sleeve guides positioning of a needle cap (430) as seen in Figure 31.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3767

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stradella in view of Cosmai. Stradella discloses the device substantially as claimed. Even though Stradella discloses administering the fluid product in doses and providing an indicator for indicating a product amount, Stradella is silent on the injector comprising a scale up to a total number of dosages amounts present and counts down by one unit on the scale when the dispensing means or operating means is operated. Cosmai discloses an injection device having an indicator which comprises a scale (i.e. the markings) and counts down by a dosage unit when the dispensing means are operated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the indicator of Stradella with a scale as taught by Cosmai as both Stradella and Cosmai disclose devices for administering a fluid in doses and Cosmai teaches that it is well known to provide a scales so that the number of dose being administered may be monitored.

Response to Arguments

14. Applicant's arguments with respect to claims 1-5, 8, 12-14, and 16 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments filed January 16 2007 have been fully considered but they are not persuasive. As to claims 6, 7, 9, 17, and 19, the specifics of the releasing element are drawn to the releasing element projecting through an opening and dimensions of the opening limiting the movement of the releasing element. In response

Art Unit: 3767

to applicant's argument that the size of the opening of Cosmai does not set the dosage amount or size of the dose, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-

Art Unit: 3767

3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

